F024: Photodynamic Therapy in Medical and Aesthetic Dermatology

Improving Efficacy and Maintaining Safety of ALA-PDT

American Academy of Dermatology
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NO CONFLICT OF INTEREST

PDT research work awarded by:
--The American Society for Dermatologic Surgery Cutting Edge Research Grant

Advisory Board
-- Biofrontera, Ameluz
Outline

- Photodynamic Therapy – Challenges and Limitations
- Medical applications - high risk patients
- Combination field cancerization therapies
- Cosmetic approaches
- Future Goals
PDT Procedure

1. Photosensitizer
2. Skin preparation and application
3. Light exposure
4. Post treatment follow up and skin care
5-ALA

- **20% ALA** (Levulan, Kerastick®, DUSA Pharmaceuticals)
  - 2 sealed glass ampoules
  - 354 mg δ - ALA hydrochloride powder
  - 1.5 ml hydroalcoholic solvent
  - Crushed within the applicator, at the time of use
  - Hand shaken, 3 min, to dissolve δ - ALA

- **10% ALA gel**, aminolevulinic acid hydrochloride (Ameluz®, Biofrontera)
  -- Direct application to skin
  -- Lesion and field directed
Topical δ - ALA

- 1999: FDA Approved for the treatment of AK
- 20% δ-ALA incubated for 14-18 hours
- Activation by light at 400-410 nm (16 min)
- Targets dysplastic proliferating and malignant epidermally derived and immune cells while sparing mesenchymal tissue including dermis
- Potential for treating multiple lesions simultaneously, rapid healing, little to no scarring and excellent cosmetic result
ALA-PDT

- MAL Metvix/Metvixia (Galderma, Lausanne, Switzerland) - red light: AKs, BD, sBCC, nBCC
- Alacare (Spirig AG, Egerkingen, Switzerland) - red light, mild AKs
Photosensitizers/ Protocols

- ALA: Hydrophilic, MAL: Lipophilic
  - No significant difference in AK and nBCC
- BF-200 ALA: nano-emulsion: stability and penetration
  - Compared to MAL in AKs: 78%-64% respectively
- Alacare /skin colored patch: occlusion
  - Better efficacy and superior to cryotherapy
- ALA-PDT: single session repeated q 4-12 weeks
- MAL-PDT: AK 1 session, BD and BCC 2 sessions 1 week apart, repeated 3 months
  - JEADV 2013;27:672-9
Light Delivery System

- Blue light source, Blue-U, DUSA Pharmaceuticals
  - Emission at narrow spectrum
  - Peak output 417 ± 5 nm
  - Exposure time: 16 minutes

- Pain management
  - Portable fan
  - Acetaminophen po
  - Ice packs
  - Topical lidocaine (3%) cream
Light Sources

- Lasers, filtered xenon arc, metal halide or fluorescent lamps, LEDs, IPLs
- Blu U (DUSA) 417 nm
- Aktilite (Galderma) 630-635 nm
- Omnilux (Phototherapeutics Ltd)
- Rhodoled (Biofrontera)
- Higher efficacy when narrow band light sources are used
Light Sources

- **Fractionation**: discontinuous illumination
  - 2-3 hour intervals, similar or increased light dose
  - Permits tissue oxygenation during dark periods
  - Higher efficacy in sBCC, not in Bowen’s Disease

- **Daylight PDT**:
  - Efficient AK eradication, cost effective, less pain
Dosimetry: Important Factors

Drug and light dose “reciprocity”?

- Light sensitizing agent
- Bio-distribution
- Incubation time
- Irradiation time point following drug delivery
- Absorption maxima of photosensitizer
- Irradiation wavelength
- Light dose (fluence)
- Light irradiance
PDT Patient Selection

- **Indications**
  - 18-95 yo
  - Skin Types I-IV
  - Extensive Photodamage
  - Not good surgical candidates
  - Patient compliance

- **Contraindications**
  - H/o Porphyria
  - Photosensitivity
  - Active infectious disease
  - Pregnancy / Lactation
  - Photosensitizing Drugs
Why patients may prefer PDT and what they want to know:

• Overall downtime
• Appearance of skin during course (0-7 days)
• Discomfort
• Clinical response
• Long term cure rates
• Final cosmetic outcome
• Compliance
• Off Label treatment
Skin Clinical End Points

- Erythema
- Edema
- Scaling
- Eschar
- Post peel erythema
- Transient pigment changes
- Recurrence

- If evidence of:
  - Alopecia
  - Scarring
  - Temporary/Permanent pigment changes
Common Challenging Factors in ALA-PDT:

• Light and Photosensitizer penetration in skin
• Conversion of ALA to PPIX
• Target selectivity
• Lesion recurrence
• Need for repeated treatments
• Discomfort
Skin Preparation and Application

- Acetone scrubs
- ALA application
Skin preparation

- Gentle curettage
- Keratolytics, overnight occlusion
- Tape stripping, microdermabrasion
- Laser resurfacing
- Micro-needle technique
- More important when nBCC, BD and sBCC than AKs are treated
- Occlusion post application: standard practice in MAL rather than in ALA
Skin Ca Prevention
Opportunities for Innovation

“FIELD” THERAPEUTIC MODALITY WITH SELECTIVE TARGETING

- Medical: Treatment of AKs and NMSCA
- Aesthetic: Acne, warts, HS, photo-rejuvenation
Actinic Keratosis & Non Melanoma Skin Cancer

- **Actinic Keratosis (AKs):** Scaly growth induced by sunlight
- **US:** Second most common reason for clinic visit
- **Adults over 40:** Prevalence 40-60%
- **Transformation to skin cancer:** 0.1-10%
- **AKs may potentially evolve to SCC and BCC**

*Criscione VD et al, Cancer 2009: 115:11:2523-2530*
Solid Organ Transplant Recipients

- AKs and Bowen’s affect up to 40% of OTR by 5 years after transplant
- Average time to develop SCC after transplant less or equal to 9 years
- SCC to BCC ratio
  - General population: 1/4
  - OTR: 2/1 to 8/1
Solid Organ Transplant Recipients

- 40%: Aks in 5 years
- Malignancy:
  - Skin: 42%
  - Urogenital: 12%
  - Lymphoreticular: 7%
  - Gastrointestinal: 6%
  - Larynx 3%
  - Bronchus 3%
  - Others

% with Skin Ca

Years since transplant
Population-Based Standard Incidence Ratios of Skin Cancer in Transplant Patients

- Squamous Cell Carcinoma (10 fold increase in mortality)
- SCC of lip
- Basal Cell Carcinoma
- Melanoma

- 40-250-fold increase
- 20 to 38-fold increase
- 10-fold increase
- 1.6 to 3.4-fold increase

Jensen et al JAAD 1999;40:17
Hartevelt Transplantation 1990;49:506
Lindelof et al BJD 2000;143;513
Braathen et al JEADV 2012: 1063-66
## Risk Factors for Skin Cancer

<table>
<thead>
<tr>
<th>Factors</th>
<th>General Population</th>
<th>Transplant Population</th>
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</thead>
<tbody>
<tr>
<td>Increasing age</td>
<td>++</td>
<td>++++</td>
</tr>
<tr>
<td>Fair skin, light hair, light eyes</td>
<td>++</td>
<td>++++</td>
</tr>
<tr>
<td>Sun exposure</td>
<td>++</td>
<td>++++</td>
</tr>
<tr>
<td>History of previous skin cancer</td>
<td>50% risk of 2nd cancer</td>
<td>&gt;70% risk of 2nd skin cancer</td>
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</tbody>
</table>
Additional Risk Factors for Skin Cancer in Organ Transplant Patients

- Duration of immunosuppression
  - Longer = more

- Intensity of immunosuppression
  - Stronger = more

- HPV infection
  - Present = more

- CD4 lymphocytopenia and Th2 dominance
  - Lower = more

M Kosmidis et al. J Immunotherapy 2010 E pub
# Recommended Dermatological Consult in SOTR

*In all situations discuss management with transplant team*

<table>
<thead>
<tr>
<th>Case</th>
<th>Frequency</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre Transplant</strong></td>
<td>Once</td>
<td>Hx, Education, Full skin exam, Report to Tx MD</td>
</tr>
<tr>
<td><strong>Post Transplant</strong></td>
<td>Yearly</td>
<td>Education, Full skin exam</td>
</tr>
<tr>
<td><strong>In situ SCC</strong></td>
<td>Q 6 mo</td>
<td>Education, Full skin examination, <em>Field cancerization</em></td>
</tr>
<tr>
<td>(Aks, Bowen's)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Early cutaneous</strong></td>
<td>Q 4-6 mo</td>
<td>Education, Full skin exam, <em>Field cancerization</em></td>
</tr>
<tr>
<td><strong>carcinogenesis</strong></td>
<td></td>
<td>Surgical removal of invasive SCC, Consider systemic retinoids, Notify Tx MD</td>
</tr>
<tr>
<td>1-4 NMSC/year</td>
<td></td>
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</tr>
</tbody>
</table>

*Christenson LJ et al, Derm Surg 2004: 30: 598*  
*Swiss Clinical Practice for skin cancer in organ transplant patients  
Swiss Med WKLY 2009:139:29-30: 407*
# Recommended Dermatological Consult in SOTR

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<thead>
<tr>
<th>Case</th>
<th>Frequency</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Moderate</strong></td>
<td>Q 2-4 mo</td>
<td>Education</td>
</tr>
<tr>
<td>cutaneous carcinogenesis</td>
<td></td>
<td>Full skin examination</td>
</tr>
<tr>
<td>5-10 NMSC/year</td>
<td></td>
<td><em>Field cancerization</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surgical removal of invasive SCC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Initiate systemic retinoids</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Contact Tx MD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Recommend reduced immunosuppression</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Consider switching to mTOR inhibitors</td>
</tr>
<tr>
<td><strong>Severe</strong></td>
<td>Q 1-3 mo</td>
<td>Education</td>
</tr>
<tr>
<td>cutaneous carcinogenesis</td>
<td></td>
<td>Full skin examination</td>
</tr>
<tr>
<td>&gt;10 NMSC/year</td>
<td></td>
<td><em>Field cancerization</em></td>
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<td>Recommend reduced immunosuppression</td>
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</table>
ALA-PDT in AKs

- Clearance 65-90% with one session
- Sessions are repeated q 4 weeks with ALA or 3 months with MAL
- 2-3 sessions may lead to complete clearance
- One year clearance 80% following ALA-PDT x2 sessions and 63-69% single session
- Cryotherapy may lead to comparable results
PDT for AKs:

- Efficacy reduced 10% on extremities vs face and scalp lesions—less thick lesions
- Less effective than cryotherapy
  
  *Br J Dermatol* 2008; 158: 994-999

- ALA PDT: Similar or better efficacy comparing to imiquimod (moderate thickness AKs: 58% vs 37% thin AKs 72%)
  
  *JEADV* 2009;23:1061-1065

- BF-200 ALA more efficacious with 1-2 sessions: 83-90% clearance  
  *Br J Dermatol* 2012;166:137-146

- Occlusion for ALA-PDT in upper extremities: higher efficacy  
  *JDD* 2012;11:12: 55-61

- Patients favor PDT due to shorter course of treatment and excellent cosmesis  
  *Br J Dermatol* 2011;164:429-433
PDT: Safe and efficient photo-chemoprevention

- ALA PDT did not affect SCC but reduced the reappearance of Aks in 2 year f/u
  - J Invest Dermatol 2006: 126: 569
- ALA-PDT x 2 (1 wk apart) significant preventive potential in AK recurrence especially in first 6 months
  - BJD 2010: 162: 171
- SOTR may benefit out of MAL- PDT session, achieving 12 month clearance 62% vs 35% in controls
  - Acta Derm Venereol 2006; 86: 25
- Cyclic ALA PDT every 4-8 weeks x 2 years resulted in 79% reduction and 95% reduction of SCCs in 12 and 24 mo f/u
  - Derm Surg 2010: 36: 652
- ALA-PDT is effective in preventing Aks and NMSCA
  - JDD 2012: 11: 593
- Field therapies play significant role in NMSCA prevention
Bowen’s Disease

- ALA and MAL PDT: Effective for lesional areas up to 3 cm
- MAL-PDT: 2 sessions, clearance up to 96%, one year recurrence as in conventional therapies (cl 68-71%)
  

- Digital, subungual and nipple BD, penile intraepithelial neoplasia (PIN)
  
  *BJD* 2008;159:1245-1266

- Areas at high risk for NMSCA and poor healing
- **Not the treatment of choice for invasive SCC**
European protocols

MAL-PDT has been equivalent to surgery for sBCC but inferior to surgery for nBCC *JEADV* 2008; 22:1302-1311

ALA-PDT for sBCC: 87% vs nBCC:53% clearance: 12 mo study review
  — *Cancer* 1997;79:2282-2308

MAL-PDT, 2 sessions one week apart: 92-97% clearance at 3 months then repeat 2nd cycle therapy as indicated;
  — 9% recurrence and 22% of responding lesions recurred in 5 years

Not recommended treatment for micro-invasive and nodular invasive BCC
nBCC – What’s New

• Tumors need to be approached based on morphology and depth
• BF-200 ALA has been effective in clearing nodular BCCs of <1 mm as much as MAL PDT
• BF-200 ALA has statistically significant higher efficacy in eradicating nodular BCCs 1-2 mm thickness than MAL PDT (3 mo f/U, non aggressive BCCS)

*Courtesy of Biofrontera*
Optimizing and potentiating PDT

Clinical practice: Applications

- Imiquimod
- 5-FU
- Chemical Peels
- Fractional Photothermolysis
- Daylight PDT

Basic Science

- Vitamin D: Sato et al., JID 2007, 127, 925
“Intensified” PDT

- AK pretreatment with 5-FU followed by ALA PDT: Intensified PDT achieves better and longer lasting results than monotherapy
- Sequential ALA-PDT followed by topical imiquimod twice weekly for 16 weeks: combination therapy significantly more effective in AK eradication vs PDT alone
- Sequential chemical peels followed by ALA-PDT
  - Intensifying PDT (Studies directed by Dr. N Konnikov, IACD 2012)
Protocol: Sequential 5 FU x 10ds and PDT x 1

- Multiple Actinic Keratosis
- Fair skin type, >60 yo
- Recurrent Aks, H/o UV exposure
- High risk NMSC

Protocol: 5 FU x 2 weeks followed by ALA-PDT
N: 7, Immunosuppressed 2

Before treatment
Sequential 5-FU and ALA-PDT

Skin Med Jan 2013; 11;(1):54-8

S/P
5-FU

12 mo
Post PDT

1 month post
AK Reduction: 5-FU-ALA PDT vs PDT (N=19)
Topical Methods to Intensify PDT in AK/NMSCA treatment

- Imiquimod
- 5-Fluorouracil
- Diclofenac
- Ingenol Mebutate
- Topical Retinoids
- Chemical Peels
- Lasers
- Cryotherapy
- Electrosurgery
- Curettage
- Surgery
- Radiotherapy
- Occlusion
- Vitamin D
- Methotrexate
Combination Field Therapies

- **Fractional Photothermolysis and MAL-PDT**
  - Fraxel SR, 2 sessions, 3 weeks apart followed by MAL-PDT
  - JDD 2007; Aug 6(8):818

- **Fractional Photothermolysis:**
  - 13.8 and 7.3 fold higher PPIX fluorescence following continuous and fractional ablation respectively
  - Experimental Dermatology 2010; 19: 806

- **Ablative Fraxel Laser Resurfacing intensifying MAL-PDT**
  - BJD 2012; 166:1262
PDT and Photorejuvenation

- Safe and useful tool
- Sallowness, fine wrinkling, mottled hyperpigmentation, telangiectasia
- Epidermal /dermal rejuvenation
  - Increase of Pro collagen I and III (max 30 days), TGF-b, epidermal proliferation and Ki67, thickening of epidermis (max 1 mo), IL-1, CK 16 (2 d),
  - Decrease of MMPs -1,-3, -12 (1 mo), P53, solar elastosis - mainly after 2 sessions
- Well tolerated
- Follow up pre/post summer months
- Equivalent to medium depth chemical peel
  - Skin Therapy Letter.com June 2012
Medical and Aesthetic Dermatology

- Acne Vulgaris
  - ALA is selectively absorbed by the sebaceous glands
  - ALA-PDT targets acne inflammatory lesions
  - Effective: longer light wavelengths
  - Uncomfortable

*JID* 2000;115:183-192
PDT in Acne Vulgaris

- ALA incubation: 1-4 hours
- Occlusion
- Activation with Blu U, PDL, IPLs, LEDs
- Red light more likely to promote sebaceous gland destruction
- Complete clearance is achieved after 2-3 sessions
- Discomfort during PDT
Results

- Phototoxic responses of erythema, edema, scaling/peeling along with pruritus are prominent on 0-6 days in both modalities.
- Overlapping or second passing in PDL facilitates faster resolution of inflammatory acne evident in 1 week post treatment.
Results

- No residual scarring or dyspigmentation observed on both modalities
- Application of Hydroquinone along with sunscreen prior to and following treatment may facilitate good cosmetic outcomes even in skin types IV-V
The Role of Photodynamic Therapy in Acne: An Evidence-Based Review.

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- Systematic Review
- 273 Publications
- Excluded: Reviews, in vitro trials, non English articles
- Included 69 clinical trials, two retrospective studies, four case reports
- Oxford Center for Evidence Based Medicine level of evidence (LOE)
# Level of Evidence 1 Clinical Trials for Photodynamic Therapy for Acne

High quality, randomized, controlled (including split face) with little or no loss to follow up, large study population, significant effect size  


<table>
<thead>
<tr>
<th>Author</th>
<th>Acne severity</th>
<th>Location</th>
<th>Photosensitizer</th>
<th>Light source</th>
<th>Number of patients</th>
<th>Duration</th>
<th>Efficacy</th>
<th>Adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yin 2010 [15]</td>
<td>Moderate to severe</td>
<td>Face</td>
<td>ALA at 5, 10, 15, or 20%</td>
<td>Red light</td>
<td>180 (45 in each group, split face control)</td>
<td>4 treatments every 10 days</td>
<td>Significant reduction in acne score at all time points in all groups (P&lt;0.05). Intergroup comparisons all statistically significant (p&lt;0.05) with increasing concentration, besides between 15% and 20% (p=0.148)</td>
<td>10 pts had intolerable pain at 20% concentration. Hyperpigmentation more frequent in 15, 20% groups. One patient in 20% group with severe blistering.</td>
</tr>
<tr>
<td>Yang 2013 [78]</td>
<td>Acne conglobata</td>
<td>Face</td>
<td>5% ALA</td>
<td>Red light</td>
<td>75 (40 control)</td>
<td>3 treatments occurring every 10 days</td>
<td>Treatment group had statistically significantly higher cure rate (87.5% vs 62.86%, p&lt;0.01) and response rate (100% vs 91.43%, p&lt;0.005) than control</td>
<td>21.88% of patients in treatment group reported mild to moderate erythema and edema; 15.63% reported severe erythema and edema</td>
</tr>
<tr>
<td>Chen 2015 [70]</td>
<td>Moderate to severe</td>
<td>Face</td>
<td>5% ALA</td>
<td>Infrared light</td>
<td>50 (25 control)</td>
<td>3 treatments every week</td>
<td>Total effective rate was 83.3% at 6 weeks, statistically significant over control</td>
<td>7 patients endorsed burning, pain, erythema with treatment. 3 had transient hyperpigmentation. 2 had acute acneiform lesions that resolved</td>
</tr>
<tr>
<td>Study</td>
<td>Severe/Moderate/Variable</td>
<td>Location</td>
<td>Photodynamic agent</td>
<td>Light source</td>
<td>Application</td>
<td>Treatment</td>
<td>Findings</td>
<td>Adverse effects</td>
</tr>
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</tr>
<tr>
<td>Horfelt 2006 [79]</td>
<td>Moderate</td>
<td>Face</td>
<td>160mg/g MAL</td>
<td>Red light</td>
<td>30 (split faced control)</td>
<td>2 treatments, 2 weeks apart</td>
<td>Median reduction of 54% in the PDT group vs 20% reduction in control group</td>
<td>70% had some adverse effect in PDT group, pain, erythema, swelling most common; all mild to moderate in severity.</td>
</tr>
<tr>
<td>Pariser 2016 [18]</td>
<td>Severe</td>
<td>Face</td>
<td>80 mg/g MAL-</td>
<td>Red light</td>
<td>153 (53 control)</td>
<td>4 treatments every 2 weeks</td>
<td>MAL significantly larger decrease in inflammatory lesion counts than control (-15.6 vs -7.8, p&lt;0.05); no significant difference in non-inflammatory lesions.</td>
<td>Pain and erythema similar between groups</td>
</tr>
<tr>
<td>Moftah 2016 [21]</td>
<td>Variable</td>
<td>Trunk</td>
<td>Liposomal methylene blue gel</td>
<td>IPL</td>
<td>35 (split backed control)</td>
<td>1 treatment</td>
<td>PDT group had statistically significant improvement in inflammatory lesion count when compared to control (56.4% vs 34.1% reduction, p&lt;0.005)</td>
<td>More pain in PDT group than in control (mean reported severity 7.8 vs 4.64, respectively); photosensitizer caused staining, pruritus, desquamation</td>
</tr>
<tr>
<td>Kwon 2016 [52]</td>
<td>Variable</td>
<td>Face</td>
<td>1.5% 3-butenyl ALA</td>
<td>Daylight</td>
<td>46 (23 control)</td>
<td>Gel applied every other day for 12 weeks</td>
<td>Decrease in inflammatory and non-inflammatory counts in treatment group were 58.0% (p&lt;0.05) and 34.1% (p&lt;0.05), respectively</td>
<td>5 patients reported erythema, pain, and dryness in treatment group</td>
</tr>
</tbody>
</table>
PDT-Acne: Algorithm
# PDT reaction management

<table>
<thead>
<tr>
<th>Before</th>
<th>Post 5-FU</th>
<th>Post PDT</th>
<th>3 Days</th>
<th>1 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cool mist / Ice</td>
<td>Topical Mupirocin 2%</td>
<td></td>
<td>Systemic antibiotics</td>
<td></td>
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<tr>
<td>TAC 01%</td>
<td>Hydroquinone</td>
<td></td>
<td>Systemic antivirals</td>
<td></td>
</tr>
<tr>
<td>Pain control</td>
<td>Moisturization/SPF</td>
<td></td>
<td>Specialty referral</td>
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</tr>
</tbody>
</table>
Pain management

- Important Factors:
  - Number, size, anatomic location of lesions
  - Monitoring: Visual Analog Scale (VAS)
- The redder the area, the more pain experienced and the better the treatment outcome
- Ice, cool air, cool mist during and post PDT
- Topical capsaicin 0.1% 3-4 days prior to PDT
  - Sandberg et al, Acta Derm Venereol 2006;86: 404-408
- Nerve blocks
Incorporating PDT to practice

- Easy to perform / no additional staff required
- Training: simple, still needs to be very thorough
- Flexibility in light source application
- No significant space requirements
- Patient education/consultation: pre and post care
Incorporating PDT to practice

- AKs easier to approach than acne
- Follow up periodically if severe AKs and photodamage, history of NMSCA, Bowen’s Disease and chronic immunosuppression
  - Follow ups: 3, 6, 12 months
- In sunny periods may schedule patients in afternoon
- Cost and reimbursement
  - Light source
  - Pre authorization contacting insurance, if indicated